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U. S. DISTRICT COURT EASTERN DISTRICT OF MO ST. LOUIS

# UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

UNITED STATES OF AMERICA, and the	:	
States of CALIFORNIA, COLORADO,	:	
CONNECTICUT, DELAWARE, FLORIDA	<b>\</b> :	
GEORGIA, HAWAII, ILLINOIS,	:	
INDIANA, LOUISIANA, MARYLAND,	:	
MASSACHUSETTS, MICHIGAN,	:	No
MINNESOTA, MONTANA, NEVADA,	:	
NEW HAMPSHIRE, NEW JERSEY,	:	Judge
NEW MEXICO, NEW YORK,	:	
NORTH CAROLINA, OKLAHOMA,	:	
RHODE ISLAND, TENNESSEE, TEXAS,	:	
VIRGINIA and WISCONSIN,	:	
THE DISTRICT OF COLUMBIA and the	:	
CITY of CHICAGO	:	COMPLAINT
	:	AND JURY DEMAND
ex rel. BRADLEY SLADE, Relator,	:	
Plaintiffs,	:	Filed Under Seal pursuant to
i minis,	:	31 U.S.C. § 3730 (b)(2)
v.	:	
	:	JURY TRIAL DEMANDED

ALLERGAN, INC. and ALLERGAN USA, INC.

Defendants.

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## I. INTRODUCTION

- 1. Qui tam Relator Bradley Slade brings this action in the name of the United States Government, the State Governments of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and the District of Columbia, and the City of Chicago ("States"), for false claims that were submitted or caused to be submitted to the United States Government and the Individual States by Defendants Allergan, Inc. and Allergan USA, Inc. (collectively referred to as "Allergan").
- 2. Allergan engaged in a large number of illegal kickbacks in which high-prescribing physicians received free samples of Botox Cosmetic and Juvederm, rewarding them for their use of therapeutic Botox. Allergan rewarded physicians with Juvederm samples and cosmetic-labeled Botox samples, including rewarding physicians using Botox for both therapeutic and cosmetic purposes. Sales representatives in the Allergan Facial Aesthetics division where Relator Slade worked regularly called on physicians who administered Botox for both therapeutic and cosmetic use.
- 3. This case is brought pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. § 3729 et seq., and pursuant to analogous provisions of state and local law, to recover treble damages and civil penalties on behalf of the United States of America and the Individual States, arising from false or fraudulent claims for reimbursements for prescription drugs that were submitted or caused to be submitted by Allergan to federal government-funded programs including, without limitation, Medicaid, Medicare, the Federal Employees Health Benefits Program, and TRICARE/CHAMPUS, in violation of the False Claims Act. The False

Claims Act specifically proscribes Allergan's conduct involving illegal kickbacks, and thus the submission of false or non-reimbursable claims to Medicaid and other government-funded health programs. The drugs encompassed by this complaint include Botox, Botox Cosmetic, and Juvederm.

- 4. Relator Bradley Slade, a former sales manager for Allergan, became aware of Allergan's False Claims Act violations and other illegal practices in the course of his work promoting the company's products in institutions and physicians' offices.
- 5. Defendants' False Claims Act violations and its various marketing schemes corrupted the independent medical judgment of physicians, unlawfully increased costs to the United States for prescription drugs, and risked patients' health by improperly influencing physicians' decisions about whether to prescribe drugs.
- 6. Allergan's kickback scheme involved physicians who used Botox and Botox Cosmetic for both cosmetic and theraputic uses, whereby Allergan sales representatives provided free samples of Botox, Botox Cosmetic, and Juvederm to "high prescribing" physicians and institutions that provided services reimbursable under Medicare and Medicaid. These free samples were intended to reward physicians for prescribing Botox for therapeutic use and encourage physicians to increase prescribing for therapeutic uses, including uses not indicated by the product's FDA-approved label.
- 7. Defendants knew or should have known that its unlawful activities would cause physicians and other healthcare professionals to routinely file false claims for reimbursement from the Federal and state governments in violation of the False Claims Act, and involved violations of the Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et seq., the Food and Drug Administration and Modernization Act of 1997, 21 U.S.C. § 351 et seq. and 21 U.S.C. § 360aaa

et seq., the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statute, 42 U.S.C. § 1320a et seq., the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, and similar State laws.

- 8. Because of Allergan's unlawful promotion scheme, patients receiving Allergan prescription drugs for unapproved and unproven uses received no assurance that their doctors were exercising their independent and fully-informed medical judgment.
- 9. Defendants' scheme illegally increased the market share for its products by inducing physicians to prescribe medications they would not otherwise have prescribed but for the receipt of the kickbacks and/or other illegal marketing efforts. The Federal and State governments consequently paid enormous sums for reimbursement claims that they would have rejected had each been aware of Allergan's illegal actions. Moreover, as a result of Allergan's illegal promotions, the public over-utilized Allergan drugs and prescription drug costs to the Federal and State governments increased, while Allergan reaped illegal profits.
- 10. Relator has direct and independent personal knowledge of the Defendants' illegal marketing practices as a result of his extensive experience with the company during and after his employment and his contacts with physicians, hospitals, and other health care institutions.

  Relator brings this action on behalf of himself, the United States of America, and the States for violations of the United States and State False Claims Acts.

#### II. JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction to this Court over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court also has subject matter jurisdiction over the counts relating to the State False Claims Acts pursuant to 31 U.S.C. §

3732(b), as well as supplemental jurisdiction over the counts relating to the State False Claims Acts pursuant to 28 U.S.C. § 1367.

- 12. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in this state and this judicial district. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because at least one act proscribed by 31 U.S.C. § 3729 occurred in this district.
- 13. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint is filed under seal and will remain under seal for a period of at least 60 days from its filing date or such other date as is required by law or the Court so orders, and shall not be served upon the Defendant unless the Court so orders.
- 14. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, or investigation, from the news media, or in any other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730 (e)(4)(A), amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010). Relator has, however, affirmatively disclosed the allegations herein to the United States Government and the *qui tam* States, including prior to filing this Complaint.
- 15. To the extent that there has been a public disclosure of the information upon which the allegations of this Complaint are based that is unknown to Relator, Relator is an original source of this information as defined in 31 U.S.C. § 3730(e)(4)(B), amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010) and similar state law provisions. Relator possesses direct and independent

knowledge of the information as a result of an extensive independent investigation he personally conducted into Defendants' wrongdoing, which he acquired in the course of his employment with Defendants and thereafter, as a result of his investigation. Relator voluntarily provided the government with this information prior to filing this action. *See* 31 U.S.C. § 3730(e)(4).

## III. PARTIES

- Aesthetics division. He was a regional manager at Allergan from June 2008 through October 2008 in the Heartland Region, which covered six states: Oklahoma, Arkansas, Tennessee, Missouri, Southern Illinois, and Kansas. As regional sales manager, he was responsible for supervising nine business development managers ("BDMs") in his territory. Business Development Managers are company sales representatives who promote the sale of Allergan facial aesthetic products such as Botox and Juvederm by visiting physicians in their offices.
- 17. Mr. Slade was a highly regarded pharmaceutical sales manager and was heavily recruited for his position at Allergan. Prior to working at Allergan he was a sales manager at Organogenesis, Inc., where he managed the top sales team in the United States. Mr. Slade has approximately 15 years of experience in the pharmaceutical sales industry.
- 18. Defendant Allergan, Inc. is headquartered in Irvine, California and is engaged in the business of manufacturing, marketing, and selling prescription drugs and other products for the prevention, diagnosis, and treatment of diseases throughout the world, with significant sales in the United States. It is engaged primarily in the developing, manufacturing and marketing a broad range of prescription and non-prescription products in the specialty areas of eye care, neurosciences, medical aesthetics, obesity intervention, medical dermatology, and urology. Defendant Allergan USA, Inc. is a subsidiary of Allergan, Inc. and specializes in drugs for

genito-urinary and women's health. All references in this Complaint to "Allergan" with regard to liability under the False Claims Act and analogous state or local law are intended to apply to both legal entities, unless specifically otherwise stated.

19. Allergan's reported worldwide sales exceeded \$4.8 billion in 2010. Allergan employs more than 9,000 people worldwide.

# IV. REGULATORY FRAMEWORK

## A. Federal Government Health Programs

- 20. The Federal and State governments, through government health programs such as Medicaid, Medicare, TRICARE, and government employee health benefit plans, are among the principal purchasers of Allergan products for therapeutic uses.
- 21. Medicare is a Federal government program primarily benefitting the elderly that was created by Congress in 1965 when it adopted Title XVIII of the Social Security Act.

  Medicare is administered by the Center for Medicare and Medicaid Services. Medicare Part D covers most self-administered prescription medications under the Medicare Prescription Drug Improvement and Modernization Act of 2003. Medicare Part B covers injectable drugs that are not typically self-administered by patients or are billed incident to services provided in a physician's office.
- 22. Medicaid is a public assistance program that provides payment of medical expenses to low-income and disabled patients. Congress created Medicaid at the same time it created Medicare in 1965 by adding Title XIX to the Social Security Act. Funding for Medicaid is shared between the Federal government and those State governments choosing to participate in the program.

- 23. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid often provides more expansive coverage than does Medicare. State Medicaid programs must follow federal guidelines, which place restrictions on the drugs and drug uses that the federal funds may be used to purchase through state Medicaid programs.
- 24. Medicaid coverage for prescription drugs is broad. Nearly every state has opted to include basic prescription drug coverage in its Medicaid plan.
- 25. TRICARE is the health care system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers. Military prescription drug benefits are provided through three programs: military treatment facility outpatient pharmacies, TRICARE contractor retail pharmacies, and a national contractor's mail-order service.
- 26. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for nearly 8.7 million federal employees, retirees, and their dependents.

  FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan.

  FEHBP plans are managed by the Office of Personnel Management. The federal government

also provides health benefits through other programs, including, but not limited to, those administered by the Department of Labor.

#### B. The False Claims Act

- 27. Originally enacted in 1863, the False Claims Act was substantially amended in 1986 by the False Claims Amendments Act. The 1986 Amendments enhanced the government's ability to recover losses sustained as a result of fraud against the United States. The Act was again amended in 2009 and 2010, further strengthening the law.
- 28. The False Claims Act provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the government for payment or approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a)(1), (2). The False Claims Act empowers private persons who have information regarding a false or fraudulent claim against the government to bring an action on behalf of the government and to share in any recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the government conducts an investigation of the allegations in the complaint and determines whether to join the action.
- 29. Knowingly paying kickbacks or undisclosed price discounts to physicians to induce them to prescribe a reimbursable drug, and promoting off-label uses of such drugs by a person who seeks reimbursement from a federal government health program for the drug, or who causes another to do so, while certifying compliance with the Medicare Fraud & Abuse/Anti-Kickback Statute, the Medicaid Rebate Statute, and the Food, Drug and Cosmetics Act (or while causing another to so certify), or billing the government as if in compliance with these laws, violates the False Claims Act.

# C. The Medicare Fraud & Abuse/Anti-Kickback Statute

- 30. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a –7b(b), which also covers Medicaid, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by fines of up to \$25,000 and imprisonment for up to 5 years.
- 31. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals, or from receiving remuneration that takes into account the volume or value of any referrals or business generated. 42 C.F.R. § 1001.952(f). Remuneration paid to providers is an illegal kickback when it is paid to induce or reward the drug prescriptions written by physicians. Kickbacks are harmful to public policy because they increase the expenditures paid by government-funded health benefit programs by inducing medically unnecessary use of prescription drugs and excessive reimbursements. Such kickbacks also reduce a patient's health care choices because they can cause physicians to prescribe drugs based on the physician's own financial interests rather than the best interests of the patient.
- 32. The Medicare Anti-Kickback Statute provides eight statutory exceptions from its statutory prohibitions, and certain regulatory "safe harbors" have been promulgated to exclude certain types of conduct from the reach of the statute. 42 U.S.C. § 1320a-7(b)(3). None of the available statutory exceptions or regulatory safe harbors protect the Defendants' conduct in this case.

- authorizes the exclusion of any individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party violated the Medicare Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended the Act to include administrative civil penalties of \$50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration, offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, solicited, or received for a lawful purpose. 42 § U.S.C. 1320a-7a(a)(7).
- 34. As detailed below, Allergan's marketing of Botox and other drugs repeatedly violated the provisions of the Anti-Kickback Statute and the False Claims Act because Allergan's improper kickbacks and incentives induced physicians to prescribe Botox when they otherwise would not have, and many of those prescriptions were paid for by Medicaid and other government funded health insurance programs.

#### D. The Medicaid Rebate Statute

35. The Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, is designed to return money to the Medicaid program in the form of rebates from drug manufacturers. Federal law provides that drug manufacturers must pay rebates to the states to ensure that the Medicaid program is paying the lowest price at which the manufacturer sells a covered outpatient drug to any purchaser in the United States, inclusive of cash discounts, free goods, kickbacks, volume discounts, and rebates. The "best price" provision is intended to ensure that the government is being provided the lowest price on drugs.

- 36. To have their drugs eligible for Medicaid payment, all drug manufacturers must provide "best price" information to the Centers for Medicare and Medicaid Services ("CMS").

  CMS uses this "best price" information to calculate the rebates payable to the Medicaid program.
- 37. Drug manufacturers provide both "best price" information and Average Manufacturer Price information to CMS. CMS then calculates a unit rebate amount, and provides that information to state Medicaid agencies. The states then consider utilization data provided by pharmacies, and the unit rebate amount, to calculate the rebate owed to them by the manufacturer. The entire system, however, relies upon manufacturers honestly conveying to CMS correct "best price" information and Average Manufacturer Price information. Any overstatement of the best price, whether intentional or unintentional, will cause an underpayment in rebate amounts.
- 38. The Medicaid Rebate Statute states, in part, that the term "best price" "shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section)." 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I).
- 39. The Federal government has great financial interest in the program. The Medicaid Rebate Statute provides that amounts received by the States under the "best prices program" shall be considered to be a reduction in the amount expended under the State Medicaid Plan for purposes of calculating the federal contributions to State Medicaid programs. 42 U.S.C. § 1369r-8(b)(1)(B).
- 40. As a result of pervasive "best price" fraud, the Office of the Inspector General of the United States Department of Health and Human Services promulgated compliance materials on May 5, 2003, which observed that manufacturers have "a strong financial incentive to hide de

facto pricing concessions" (in particular, kickbacks and price discounts) that could affect "best price" calculations and trigger increased Medicaid rebates. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735 (May 5, 2003). The Office of the Inspector General instructed manufacturers to report "best prices" which "accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to all purchasers." *Id.* at 23733-23734.

According to the Office of the Inspector General, "pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes." *Id.* 

41. The Medicaid program reimburses doctors only for "covered outpatient drugs" for which a rebate is paid by the drug's manufacturer. 42 U.S.C. § 1396b(i)(10). Each state Medicaid program has the power to exclude any drug from coverage if the prescription is not issued for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B). A "medically accepted indication" includes only those indications approved by the FDA, and those off-label uses that are "supported by one or more citations included, or approved for inclusion, in any of the compendia" listed in the statute. 42 U.S.C. § 1396r-8(k)(6).

## E. Stark Law - The Medicare/Medicaid Self-Referral Statute

42. The Medicare-Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn *et seq.*, known as the "Stark Law," prohibits a pharmaceutical manufacturer from paying remuneration to physicians for referring Medicaid patients to the manufacturer for certain "designated health services," including drug prescriptions, where the referring physician has a nonexempt "financial relationship" with that manufacturer. 42 U.S.C. § 1395nn(a)(1), (h)(6). The Stark Law provides

that the manufacturer shall not cause to be presented a Medicaid claim for such prescriptions. The Stark Law also prohibits payment of Medicaid claims for prescriptions rendered in violation of its provisions. 42 U.S.C. § 1395nn(a)(1), (g)(1). Allergan's marketing of Botox and other drugs violated the Stark Law and the False Claims Act because Allergan's unlawful payments and services to prescribing physicians induced those physicians to prescribe Botox and other Allergan drugs when they would otherwise not have, and many of those prescriptions were paid for by Medicaid and other government-funded health programs.

## F. State False Claims Acts

43. Twenty-seven states, the District of Columbia, and the City of Chicago ("the States") have False Claims Acts that mirror the language of the Federal False Claims Act. Some state false claims acts relate only to Medicaid programs, while other statutes prohibit the presentation of false claims for payment in any context.

### V. SPECIFIC ALLEGATIONS OF DEFENDANTS' VIOLATIONS OF LAW

#### A. Illegal Kickbacks

#### 1. Botox and Botox Cosmetic

- 44. Botox and Botox Cosmetic are the trade names for OnabotulinumtoxinA, a botulinum toxin. OnabotulinumtoxinA is a neurotoxin produced by a strain of the bacteria *Clostridia botulinum*. The proteins produced by the bacteria are purified and modified into an injectible form. When injected, the botulinum toxin has the effect of blocking muscle contraction or gland activity at the injection site. Botulinum toxins block muscle contractions by preventing the action of acetylcholine, a neurotransmitter that signals muscle cells to contract.
- 45. Botox comes in two forms, Botox Therapeutic and Botox Cosmetic. Both forms are the same drug; the only difference is the label. Botox and Botox Cosmetic are both available

only by prescription. The drugs are identical whether the drug is used for therapeutic or cosmetic purposes. Approximately half of the Botox used in the United States is used for therapeutic purposes and half is for cosmetic purposes. Therapeutic Botox use is typically paid for by insurance or government health care programs, while Botox used for cosmetic purposes is typically paid for by the patient and not insurance or other third-party payors.

- 46. On April 30, 2009, the FDA changed the generic drug names of botulinum toxin products sold in the United States in order to avoid confusion among the different formulations and potencies of botulinum toxin products. Prior to that time, Botox and Botox Cosmetic were listed under the generic name of botulinum toxin type A. The change in Botox's generic name from botulinum toxin type A to OnabotulismtoxinA did not change the formulation, trade name, or approved indications for Botox or other botulinum toxin products.
- 47. Botox has both therapeutic and non-therapeutic uses. Although Botox is best known for its cosmetic uses in reducing facial wrinkles and lines, the drug was first approved to treat certain neuromuscular conditions. Therapeutic Botox is currently approved for the following indications:
  - a) chronic migraine in adults who have 15 or more days each month with a headache lasting 4 or more hours each day;
  - b) upper limb spasticity (increased muscle stiffness in elbow, wrist, and finger muscles in adults);
  - c) cervical dystonia (spasm of the muscles of the neck) to reduce abnormal head position and neck pain caused by the muscular spasm;
  - d) severe primary axillary hyperhidrosis (excessive armpit sweating) when the use of topical agents are ineffective; and
  - e) the treatment of strabismus (misaligned or "lazy" eyes) and blepharospasm (uncontrollable blinking) in people 12 years and older.

Botox Cosmetic is indicated for injection into the muscles to temporarily improve the look of moderate to severe "frown lines" between the eyebrows (known as glabellar lines) in adults less than 65 years old.

53. Botox and Botox Cosmetic are distributed worldwide. Allergan forecasts global sales of Botox in 2011 to reach or exceed \$1.5 billion.

#### 2. Juvederm

- 54. Juvederm is exclusively for cosmetic use and is typically paid for by the patient. Juvederm is a hyaluronic gel indicated for cosmetic injection into the mid-to-deep dermis (the layer of the skin beneath the skin's surface) for correction of moderate to severe facial wrinkles and folds, including the nasolabial folds, the so-called "laugh lines" that run from the bottom of the nose to the corner of the mouth.
- 55. Juvederm works by replacing hyaluronic acid in the skin, which is a naturally occurring compound. Among other things, hyaluronic acid hydrates the skin and adds volume, contributing to the overall appearance of the skin. The ability of cells to produce hyaluronic acid diminishes with age, often resulting in the formation of wrinkles and folds as the skin loses volume.
- 56. Allergan currently markets and sells an injectable hyaluronic gel in the United States under five distinct trade names: "Juvederm," "Juvederm Ultra," "Juvederm Ultra Plus," "Juvederm Ultra XC," and "Juvederm Ultra Plus XC." Inclusion of "XC" to the Juvederm trade name indicates the addition of the anesthetic lidocaine to the Juvederm formula, which was approved in 2010 by the FDA for use with Juvederm. Inclusion of "Plus" to the Juvederm trade name indicates the formula is in a more dense form than the basic formula. When injected into the skin, the "Plus" formula produces a greater volume effect to deeper wrinkles and facial folds than does the basic formula. All forms of Juvederm are available by prescription only.

## 3. Kickback Schemes Involving Botox and Juvederm

- 57. Allergan engaged in kickback schemes involving the distribution of samples of Botox and Juvederm. Allergan Heartland Region sales representatives frequently offered Juvederm samples to reward Botox physician customers and offered Botox samples to reward Juvederm purchasers. Physicians used these Juvederm samples to treat cosmetic patients and charged the patients for the Juvederm. With regard to Botox, physicians charged both government and private payors for the Botox used, however, Allergan did not restrict the Botox to use for only cosmetic patients. Relator Slade believes that these practices continue in the Heartland Region.
- 58. Each Allergan Business Development Manager was given 40 100 ml Botox vials each quarter to distribute to physician customers. Business Development Managers had discretion to determine who received the samples, except that physicians were to receive no more than 40 sample vials of Botox annually. Each Botox sample vial had a market value of approximately \$500. Once samples were requested by the Business Development Managers, Botox samples were shipped to physicians directly via a distribution center.
- 59. Business Development Managers received a supply of Juvederm samples to distribute as they wished. Unlike Botox samples, there were no limits on how many Juvederm samples a physician could receive. Unlike the Botox samples, Business Development Managers delivered Juvederm samples in person to physicians' offices. Each Juvederm sample box contained two filled syringes. The Juvederm samples' market value was approximately \$500 a box, \$250 per syringe.
- 60. Allergan regional managers received allotments of Botox and Juvederm samples.

  Relator Slade received 90 Botox vials each quarter, a \$45,000 value, along with substantial

Juvederm samples. Relator Slade's supervisor, Director of Sales Chris Harper, also received sample allocations of the two products. Managers would often reallocate their samples to Business Development Managers in order to supplement the Business Development Managers' individual allotments. Allergan had approximately 30 regional managers like Relator Slade, each of whom received 90 sample vials per quarter. The value of the samples received by the regional sales managers annually was approximately \$5,400,000. This figure does not include the value of samples received by sales representatives or higher-level managers such as Chris Harper.

- 61. Sales representatives in the Heartland Region frequently provided "staff training vials" to physicians, ostensibly for training purposes or to assess the efficacy of the product.

  Instead, physicians used these "training vials" to inject patients at full charge, as if the physician bought the Botox. Relator Slade questioned this practice and reported it to his immediate supervisor, Chris Harper, who told Mr. Slade that this practice was legal.
- 62. In July 2008, Relator Slade received a request from Jenny Wickenhauser, a Business Development Manager he supervised, for samples of Botox Cosmetic for a physician whom she called on, Dr. Jay Pepose, a St. Louis ophthalmologist. Pepose Vision was one of the largest Allergan ophthalmic accounts in the United States and a large purchaser of Allergan products, including Restasis. Patients treated at Pepose Vision included those covered by Medicare, Medicaid, and other federal health programs. The request originated with a sales representative from Allergan's ophthalmologic division, who also called on Dr. Pepose. The ophthalmologic representative indicated that Dr. Pepose intended to start a cosmetic practice in his office and needed samples to begin. Ms. Wickenhauser expressed doubt that Dr. Pepose actually was interested in starting a cosmetic practice because he had made similar requests in

the past, but had never initiated a cosmetic practice. Instead, he injected his office staff with the samples. Ms. Wickenhauser also stated that she believed that the samples were a reward for Dr. Pepose's large prescription volume of Restasis, an Allergan product used to treat chronic dry eye. In the past there had been a sales "bump" or increase in orders and prescriptions from Dr. Pepose for Allergan ophthalmic products after Botox samples were delivered.

- 63. Relator Slade expressed concern to his immediate supervisor, Chris Harper, that the Botox samples were an unlawful kickback to Pepose Vision. Mr. Harper decided that Ms. Wickenhauser should deliver the samples as requested and later follow up with Dr. Pepose to help him develop a cosmetic practice. The samples were delivered, but the Pepose practice thereafter refused to meet with Ms. Wickenhauser about developing a cosmetic practice.
- 64. Relator Slade notified Mr. Harper that Pepose Vision did not appear to be interested in starting a cosmetic practice and that giving Dr. Pepose the samples was an improper kickback for his Restasis prescriptions. Mr. Harper told Relator Slade that he would review the situation and respond to him, but he never did.
- 65. Common Heartland Region practice was for sales representatives to give free samples to institutions providing services reimbursable under Medicare and Medicaid. Relator Slade reported to his manager about an arrangement to provide free samples of Juvederm to Dr. Dee Anna Glaser, a physician affiliated with St. Louis University Hospital. Dr. Glaser's practice included Botox use for both cosmetic and therapeutic purposes. Her therapeutic use patients included those covered by Medicare, Medicaid, and other federal health programs.
- 66. Company policy against kickbacks prohibited offering Dr. Glaser a rebate on purchases of Juvederm because of her hospital affiliation. This resulted in a higher per-unit cost of Juvederm to Dr. Glaser as compared with the price for doctors who were not affiliated with

hospitals. Dr. Glaser complained about this situation to Renee Schmidt, the Business

Development Manager in St. Louis. Ms. Schmidt then informed Relator Slade of Dr. Glaser's complaints.

- 67. When Relator Slade discussed Dr. Glaser's complaints with Chris Harper, Mr. Harper decided that because she was an important customer, Dr. Glaser should be given samples of Juvederm to make up for the rebate that she could not be paid, despite the company's anti-kickback policy. Relator Slade informed Mr. Harper that this was an illegal kickback and contacted the Allergan marketing department for confirmation. Mr. Harper then told Relator Slade and Ms. Schmidt that he had contacted Allergan's legal department, but that they should "take care of Dee Anna" by continuing to provide samples to Dr. Glaser until instructed otherwise. Relator Slade again objected to this practice.
- 68. Relator Slade learned that Ms. Schmidt provided Dr. Glaser with one free Juvederm box for every five Juvederm boxes that she ordered. The free box came from Ms. Schmidt's sample allotment. To avoid detection of this arrangement, Ms. Schmidt delivered these samples to Dr. Glaser at a clinic outside the hospital or delivered them to another physician, who then passed them on to Dr. Glaser, thereby bypassing normal hospital logging and reporting channels for sample storage required by FDA law. Relator Slade reported this activity to Mr. Harper and told him he believed it was improper and illegal.

# 4. Using Samples to Induce Purchasing

69. In July 2008, Relator Slade began to notice that certain Business Development

Managers were requesting large numbers of samples from his stock. Relator Slade was

concerned that the number requested by Rod Nerad, an Oklahoma City Business Development

Manager, far exceeded the amount for legitimate sampling purposes. Mr. Nerad's requests came

near the end of the quarter, raising another concern for Relator Slade. Because Business

Development Managers are paid commissions quarterly, he suspected the increased sample request was being used to induce physicians to buy more products and therefore increase the Business Development Manager's commission before the quarter's end. When Relator Slade reported this activity to Chris Harper, Mr. Harper told him that he did not believe it was inappropriate.

- 70. In September 2008, Relator Slade began asking the Business Development Managers who he supervised to provide more detailed information when they requested more samples from him. One, Renee Schmidt, gave Relator Slade a spreadsheet showing where she had delivered samples or committed to deliver them for the quarter. On the spreadsheet, Ms. Schmidt left a note: "Brad this doesn't leave much to make deals with at the end of the quarter." Ms. Schmidt's note indicated that by "making deals," sales representatives were using samples either to induce purchases or as gifts for the physicians' personal benefit.
- 71. Sales representatives in the Heartland Region used a worksheet that was commonly used among Allergan sales representatives nationwide. The worksheet was used to calculate the effective per-vial cost to a physician of Botox or Juvederm after samples were taken into account. The worksheet had spaces for the amount of vials purchased by the physician, the amount of vials received as free samples, and a space to calculate the per-vial cost when the number of samples became known. This worksheet was created by an Allergan sales manager in Atlanta, Dustin Sjuts, and was distributed nationwide throughout the company. It was also used as an example at sales meetings. Relator Slade witnessed the Business Development Managers in his territory using the worksheet during field rides. The worksheet and cost calculations show that sales representatives were aware that physicians were not using

sample vials for legitimate testing or comparison purposes, but were instead using them to treat paying patients.

# 5. Services and Samples Provided to Practices

- 72. It was a common Heartland Region practice to give Botox and Juvederm samples to physicians and their staff. These samples were ostensibly provided to show the product's effectiveness to patients visiting the office and encourage them to seek cosmetic Botox and Juvederm treatment. Samples were provided to practices that also provided therapeutic Botox in addition to cosmetic procedures. Providing physicians or staff members with free product, that they would have otherwise paid for themselves, constitutes a kickback.
- 73. Allergan also provided valuable business consulting services to physicians to induce them to purchase Allergan products. The consultants were Allergan employees who met with medical practices to give them advice on how to increase their profitability with Botox use. For instance, consultants would review a practice's business and advise how to increase the procedure-dollar per hour or how to recruit more patients to receive cosmetic Botox treatments. Business consulting services were provided to practices that performed both therapeutic and cosmetic Botox injections. The primary consideration in providing business consulting services was the volume of Allergan products used or the potential volume, not the intended use of the product for cosmetic or therapeutic use. Allergan business consultants had access to financial statements about the practice's business, as well as other confidential information about the inner workings of the practice.
- 74. The Allergan business consultant for the St. Louis area, Jay Schroeder, used confidential information provided to him by medical practices to help the Business Development Managers increase their sales to these practices. Mr. Schroeder disclosed information about the

income of medical practices and doctor salaries to Business Development Managers, which the Business Development Managers then used in marketing Allergan products to these physicians.

# 6. Use and Exchange of Samples for Personal Cosmetic Procedures

- 75. While accompanying Rod Nerad, an Oklahoma City Business Development Manager, on a field ride in July 2008, Relator Slade was present during a conversation in which Mr. Nerad discussed giving cosmetic Botox samples to the physician in exchange for the physician injecting Mr. Nerad with therapeutic Botox. Mr. Nerad stated in this conversation that he used Botox for treating hyperhidrosis (excessive sweating).
- 76. At training for new Business Development Managers in August 2008, which Relator Slade attended as part of his management training, Business Development Managers in training were injected with Botox and Juvederm, supposedly as a way of giving them the idea of what the injection procedure was like. There was a lot of "peer pressure" for the trainees to get injected at the meeting. The Vice President of the Allergan Facial Aesthetics Division, Bob Rhatigan, brought his wife to the training session so that the trainees could observe her being injected with Botox to minimize the appearance of the tendons in the neck, an off-label cosmetic use. The injections were done to show the trainees how the cosmetic procedures are done so that the sales representatives could better sell the drug to physicians, having witnessed or experienced the procedure themselves. By performing an off-label procedure for the trainees, Allergan gave sales representatives information about off-label uses that they could use to promote the use to their physician customers. By allowing sales representatives to undergo the Botox and Juvederm procedures themselves, Allergan believed that the sales representatives could be more effective in marketing these products to physician customers, including potential customers for cosmetic services who already provided therapeutic Botox treatment.

## 7. Relator Slade's Reporting of Kickbacks and Other Unlawful Activity

- 77. Relator Slade reported his concerns about kickbacks and other unlawful activity occurring in the Heartland Region to his immediate supervisor, Chris Harper. Mr. Harper reports directly to the Vice President of Sales for the Allergan Aesthetics Division.
- 78. Relator Slade held a meeting with Chris Harper on October 1, 2008, to discuss the improper and illegal sampling practices occurring in the Heartland Region and how to address them. Relator Slade specifically mentioned the arrangements with Dr. Pepose, Dr. Glaser, and Dr. Moore, as well as the use of samples to compensate physicians for travel to attend trainings. Relator Slade also discussed the sampling practices of Business Development Managers in the territory, including Rod Nerad, and stated that he wanted to investigate these practices.
- 79. Chris Harper did not respond to the concerns Relator Slade expressed in their October 1 meeting. Three weeks later, Mr. Harper met with Relator Slade and told him that complaints had been made against him. Relator Slade was surprised, but addressed the complaints brought up by Mr. Harper.
- 80. One week later, on October 29, 2008, Mr. Harper arranged a meeting with Relator Slade. At that meeting, Relator Slade was fired, allegedly for "lack of personal judgment" and for failure to be a "good fit" with the Business Development Managers in his region.

#### **B.** Best Price Violations

81. As a result of the extensive distribution of free Botox samples, the Medicare and Medicaid programs were overcharged for Botox and the price Allergan charged the federal and state payors did not reflect the true best price. The "best prices" failed to reflect the value of the large amounts of free Botox and Juvederm samples distributed by Allergan to providers,

resulting in a lower price per unit for than the amount that Allergan represented was the best price to Medicare and Medicaid.

- 82. Allergan also misclassified accounts as cosmetic (instead of therapeutic) accounts, which allowed company sales representatives to distribute samples to physicians who also prescribed Botox for therapeutic use. Sales representatives and the physicians who accepted these samples did not track or segregate these samples to ensure that they were only used for cosmetic use.
- 83. In August 2008, Relator Slade learned that Allergan had improperly classified some sales of Botox Cosmetic as if they were therapeutic Botox. Botox Cosmetic is paid for directly by the patient, while Botox for therapeutic purposes is commonly paid for by insurance companies and government health programs. This misclassification led to the Average Manufacturer Price (AMP) and the Best Price being improperly calculated and reported to the government because free samples received by these providers were not taken into account.
- 84. Allergan classified physician accounts as either therapeutic or cosmetic, based on the volume of cosmetic Botox ordered by a physician. If a certain volume of cosmetic Botox was ordered, the physician was classified as a "cosmetic" customer and was rewarded with samples based on cosmetic Botox purchases. Allergan did nothing to avoid rewarding physicians who served both cosmetic and therapeutic customers.
- 85. Most physicians using Botox treat two kinds of patients, those seeking therapeutic treatment and those seeking cosmetic services. Commonly, physicians who have both types of patients will, therefore, have at least 20% therapeutic patients and at least 20% cosmetic patients, with the actual therapeutic-cosmetic patient distribution varying widely from one physician to another. If a provider used a certain percentage of Botox for cosmetic purposes, then that

provider was classified as a "cosmetic" customer, and was given free samples unavailable to providers classified as "therapeutic" customers. Providers were classified as "cosmetic" customers even if they provided a significant amount of therapeutic Botox treatment. If a physician's cosmetic use increased, then Allergan reclassified the provider from therapeutic to cosmetic and the responsible sales representative changed. Since many physicians ordered Botox for both cosmetic and therapeutic uses, Allergan often re-classified customers based on changes in sales.

- 86. Allergan would also reclassify an account from therapeutic to cosmetic at a sales representative's request. To request that an account be reclassified as cosmetic, Relator Slade called Allergan headquarters and left a voice mail message. Sales representatives in the cosmetic division often requested that potentially lucrative practices that treated both therapeutic and cosmetic patients be reclassified as cosmetic because company policy did not allow cosmetic sales representatives to call on accounts classified as therapeutic, and thus, these physicians could not easily be rewarded with samples.
- 87. Some physicians who only performed Botox injections for therapeutic uses on patients would occasionally request or receive Botox Cosmetic vials for use in injecting into their office staff for cosmetic purposes. Pepose Vision, an ophthalmology practice in St. Louis, was among such practices.
- 88. Sales representatives in the Facial Aesthetics Division received bonuses only for sales for cosmetic-labeled Botox. Cosmetic sales representatives were instructed not to call on accounts listed as therapeutic and not to distribute samples to therapeutic accounts.
- 89. If a physician ordered some vials of cosmetic-labeled Botox and some vials of therapeutic-labeled Botox, the cosmetic Botox sales would be credited to the cosmetic sales

representative and the sales for the therapeutic portion of the order would be credited to the therapeutic representative for that territory, even if the therapeutic representative had never called upon the practice. Physicians were able to order cosmetic- or therapeutic-labeled Botox at their own discretion.

- 90. Allergan sales representatives in the Facial Aesthetics Division were instructed to request cosmetic-labeled Botox samples for physicians without regard for whether the intended use of the sample was to be therapeutic or cosmetic.
- 91. The company did minimal tracking of samples. Botox Cosmetic samples, which were ordered by the Business Development Managers via computer and shipped directly to the physician, were accompanied by a form that the recipient physician's office was supposed to complete and return to Allergan to confirm the shipment. If the form was not returned, Business Development Managers were instructed to visit the practice to confirm that the shipment had been received. The form did not attempt to track the intended usage of the samples. There was no other logging done of the samples.
- 92. Relator Slade discovered that misclassification was common among Ron Nerad's customers in Oklahoma City. For example, an Oklahoma City area orthopedic surgeon also operated a "medi-spa," which provided elective cosmetic procedures. The Botox orders by this physician were classified as therapeutic, because his medical specialty was surgery, even though he intended to use them in his cosmetic practice. Because this Botox was intended for cosmetic use, it should not have been included in calculating the AMP and Best Price for therapeutic Botox. Additionally, the Botox pricing information reported was artificially high, because it did not take into account the value of rebates and samples provided and, thus, did not reflect the actual price paid.

- 93. It was a common practice for Allergan sales representatives in the Facial Aesthetics division to create worksheets for physician customers showing the retail price of Botox and Juvederm and the net price after samples and other discounts were taken into account. The worksheet was used with physicians who treated both cosmetic and therapeutic patients with Botox. The worksheet acknowledged that these physicians were not using the samples for legitimate sampling purposes, but were instead using them to treat paying patients. For providers who treated therapeutic patients with samples of Botox, the worksheet also contained information, such as rebates and discounts, that should have been used for calculating AMP and best prices but was not.
- 94. Under Allergan company policy, therapeutic sales representatives were not allowed to carry Juvederm samples or order Botox samples. It therefore benefited a physician to be classified as a cosmetic account or to order cosmetic-labeled Botox, because the classification would allow cosmetic sales representatives to call on that physician and leave samples. If the physician ordered cosmetic-labeled Botox, those sales would be credited to the cosmetic sales representative for sales quota and bonus purposes and the sales representative would be more willing to "make deals" with that physician by providing samples for the physician's use.
- 95. Because ordering cosmetic-labeled Botox was beneficial to the cosmetic Business Development Managers, as well as potentially beneficial for the ordering physician, many Heartland Region Business Development Managers specifically requested that physicians order Botox Cosmetic instead of the therapeutic-labeled product. Ron Nerad told physicians whom he called upon to order Botox Cosmetic for all purposes because "it's all the same." A St. Louis Business Development Manager, Renee Schmidt, and a Memphis Business Development Manager, Emily Dickerson, told Relator Slade that they advised customers to order Botox

Cosmetic regardless of the intended purpose. This strategy was not limited to the Heartland Region; it was discussed among sales representatives at national training sessions and conferences.

- 96. Juvederm samples were carried by Business Development Managers and distributed in person. Although physicians were required to sign when receiving Juvederm samples, there was no accountability or tracking of Juvederm samples other than the signature requirement. After delivering the samples, sales representatives were supposed to complete and return a mail-in card. The company, however, did not closely monitor the return of these cards and many sales representatives did not return them. The samples were not logged to document their receipt by physicians, in violation of federal laws requiring proper inventory control and accountability for sample distribution.
- 97. One St. Louis physician, Dr. Dee Anna Glaser, stored Botox vials in a mini-fridge in her office, with no separation between Botox vials that were purchased by her practice or those that were given to her as samples. There was also no segregation between cosmetic labeled Botox and therapeutic labeled Botox. Relator Slade personally saw Dr. Glaser's storage refrigerator during office visits and field rides when he accompanied Business Development Managers on sales calls to her clinic at DePere Hospital, affiliated with St. Louis University. Relator Slade did not see a log or any way of tracking the samples in this refrigerator.

# C. Prior Settlement with Allergan

98. The U.S. Department of Justice previously entered into a False Claims Act settlement with Allergan. That settlement covers conduct in the period January 1, 2001 to December 31, 2009 for the marketing of Botox for overactive bladder and neurogenic bladder and covers conduct between January 1, 2001 to December 31, 2008 for all other claims, which

included off-label marketing for Botox for headache, pain, and muscle spasms and spasticity, and unlawful payments to physicians.

- 99. The claims in this complaint are not covered by the prior settlement. The prior settlement addressed primarily off-label marketing for medical conditions outside the thenapproved FDA indications for Botox. The "covered conduct" in the settlement also included claims that "Allergan offered and paid illegal remuneration to health care professionals that was intended to induce them to promote and/or prescribe Botox." Neither the settlement nor the underlying *qui tam* complaints addressed the conduct described by Relator Slade herein. Relator Slade, through counsel, advised the Department of Justice in May 2011, in advance of filing this Complaint, of these claims. The Department of Justice acknowledged receipt but did not report that the claims and conduct were subject to the prior Allergan settlements.
- 100. Relator Slade's claims regarding the distribution of free samples of Botox and Juvederm are distinct from the claims covered by the Settlement Agreement. Relator Slade's claims relate to a kickback scheme that could only be carried out for physicians who treat both therapeutic and cosmetic patients and use both Botox and Juvederm.
- 101. The covered conduct in the settlement agreement involved off-label marketing schemes targeting physicians who only treated patients with Botox for therapeutic purposes and did not have a cosmetic practice at all, such as neurologists, pain specialists, and urologists. These physicians did not use Botox Cosmetic or Juvederm, and, therefore, did not receive free samples of these products.
- 102. The pricing scheme disclosed by Relator Slade is different that the pricing scheme covered by the Settlement Agreement. The unlawful pricing scheme disclosed by Relator Slade involves manipulation of the federally required Best Pricing information due to the

distribution of unreported free samples of Botox, Botox Cosmetic, and Juvederm, which reduced the cost to physicians who administered Botox in their offices, but did not reduce the price paid by government payors for therapeutic purchases of Botox.

103. The pricing scheme disclosed by Relator Slade also involves the misclassification of physicians and other providers based on their use of Botox for therapeutic purposes as compared to cosmetic purposes.

#### VI. CLAIMS FOR RELIEF

## **COUNT I**

(False Claims Act - Presentation of False Claims)
[31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A) as amended in 2009]

- 104. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.
- 105. Through the acts described above, Allergan and its agents and employees knowingly presented and caused to be presented to an officer or employee of the United States Government a false and/or fraudulent claim for payment or approval in violation of 31 U.S.C. § 3729(a)(1), and, as amended 31 U.S.C. § 3729(a)(1)(A).

# **COUNT II**

(False Claims Act - Making or Using False Record or Statement to Cause Claim to be Paid) [31 U.S.C. § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B) as amended in 2009]

- 106. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.
- 107. Through the acts described above and otherwise, Allergan and its agents and employees knowingly made, used, and/or caused to be made or used false records and statements in violation of 31 U.S.C. §§ 3729(a)(2), and, as amended 31 U.S.C. § 3729(a)(1)(B) in order to get such false and fraudulent claims paid and approved by the United States Government.

#### **COUNT III**

(False Claims Act - Making or Using False Record or Statement to Conceal, Avoid and/or Decrease Obligation to Repay Money) [31 U.S.C. § 3729(a)(7), 31 U.S.C. § 3729(a)(1)(G) as amended in 2009]

- 108. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.
- 109. Through the acts described above, in violation of 31 U.S.C. § 3729(a)(7) and as amended, 31 U.S.C. § 3729(a)(1)(G), Allergan and its agents and employees knowingly made, used, and caused to be made or used false records and statements to conceal, avoid, and/or decrease Allergan's obligation to repay money to the United States Government that Allergan improperly and/or fraudulently received. Allergan also failed to disclose material facts that would have resulted in substantial repayments to the United States.

# COUNT IV California False Claims Act Cal. Gov't Code § 12651 et seq.

- 110. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 111. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code § 12651 *et seq*.
- 112. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the California Medicaid Program (i.e., Medi-Cal) false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 113. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

114. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT V Colorado Medicaid False Claims Act Colo. Rev. Stat. § 25.5-4-303.5 et seg.

- 115. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 116. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act. Colo. Rev. Stat. § 25.5-4-304 *et seq.*
- 117. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Colorado Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 118. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 119. By reason of these payments, the Colorado Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT VI Connecticut False Claims Act Conn. Gen. Stat. § 17b-301a et seq.

- 120. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 121. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act. Conn. Gen. Stat. § 17b-301a et seq.
- 122. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the State and the Connecticut Medicaid Program false or fraudulent claims

for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.

- 123. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 124. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

## COUNT VII Delaware False Claims Act Del. Code Ann. tit. 6, § 1201 et seq.

- 125. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 126. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Del Code Ann. tit. 6, § 1201 et seq.
- 127. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Delaware Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 128. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 129. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT VIII Florida False Claims Act Fla. Stat. Ann. § 68.081 et seq.

130. The allegations of the preceding paragraphs are realleged as if fully set forth below.

- 131. This is a claim for treble damages and civil penalties under the Florida False Claims Act. Fla. Stat. Ann. § 68.081 *et seq*.
- 132. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Florida Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 133. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 134. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT IX Georgia False Medicaid Claims Act Ga. Code Ann. § 49-4-168 et seq.

- 135. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 136. This is a claim for treble damages and civil penalties under the False Medicaid Claims Act. Ga. Code Ann. § 49-4-168 et seq.
- 137. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Georgia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 138. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 139. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT X Hawaii False Claims Act Haw. Rev. Stat. § 661-22 et seq.

- 140. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 141. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act. Haw. Rev. Stat. § 661-22 et seq.
- 142. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 143. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 144. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XI Illinois Whistleblower Reward and Protection Act 740 Ill. Comp. Stat. 175/1 et seq.

- 145. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 146. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act. 740 Ill. Comp. Stat. 175/1 et seq.
- 147. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Illinois Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.

- 148. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 149. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XII Indiana False Claims and Whistleblower Protection Burns Ind. Code Ann. § 5-11-5.5-1 et seq.

- 150. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 151. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Law. Burns Ind. Code Ann. § 5-11-5.5-1 *et seq*.
- 152. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Indiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 153. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 154. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT XIII Louisiana Medical Assistance Programs Integrity Law La. Rev. Stat. Ann. § 46:437.1 et seq.

- 155. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 156. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law. La. Rev. Stat. Ann. § 46:439.1 *et seq*.

- 157. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and knowingly used false or fraudulent records to accomplish this purpose.
- 158. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 159. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XIV Maryland False Health Claims Act Md. Code Ann., Health-Gen. §2-601 et seq.

- 160. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 161. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act. Md. Code Ann., Health-Gen. §2-601 *et seq.*
- 162. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Maryland Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 163. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 164. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT XV Massachusetts False Claims Act Mass. Ann. Laws ch. 12, § 5(A) et seq.

- 165. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 166. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws ch. 12, § 5(A) et seq.
- 167. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 168. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 169. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT XVI Michigan Medicaid False Claim Act Mich. Comp. Laws §400.601 et seq.

- 170. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 171. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act. Mich. Comp. Laws §400.601 *et seq*.
- 172. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Michigan Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.

- 173. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 174. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT XVII Minnesota False Claims Act Minn. Stat. § 15C.01 et seg.

- 175. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 176. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act. Minn. Stat. § 15C.01 et seq.
- 177. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 178. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 179. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

# COUNT XVIII Montana False Claims Act Mont. Code Ann. §17-8-401 et seq.

- 180. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 181. This is a claim for treble damages and civil penalties under the Montana False Claims Act. Mont. Code Ann. § 17-8-401 *et seq*.

- 182. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Montana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 183. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 184. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XIX Nevada False Claims Act Nev. Rev. Stat. § 357.010 et seq.

- 185. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 186. This is a claim for treble damages and civil penalties under the Nevada False Claims Act. Nev. Rev. Stat. § 357.010 *et seq*.
- 187. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Nevada Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 188. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 189. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XX New Hampshire Medicaid Fraud and False Claims Law N.H. Rev. Stat. Ann. § 167:61-b et seq.

- 190. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 191. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law. N.H. Rev. Stat. Ann. § 167:61-b et seq.
- 192. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 193. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 194. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT XXI New Jersey False Claims Act N.J. Stat. § 2A:32C-1 et seq.

- 195. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 196. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act. N.J. Stat. § 2A:32C-1 et seq.
- 197. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the

New Jersey Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.

- 198. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 199. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

# COUNT XXII New Mexico Medicaid False Claims Act N.M. Stat. Ann. § 27-14-1 et seq.

- 200. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 201. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act. N.M. Stat. Ann. § 27-14-1 *et seq*.
- 202. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 203. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 204. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XXIII New York False Claims Act N.Y. State Fin. Law § 187 et seq.

205. The allegations of the preceding paragraphs are realleged as if fully set forth below.

- 206. This is a claim for treble damages and civil penalties under the New York False Claims Act. N.Y State Fin. Law § 187 et seq.
- 207. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New York Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox for off-label uses and used false or fraudulent records material to a false or fraudulent claim to accomplish this purpose.
- 208. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 209. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XXIV North Carolina False Claims Act N.C. Gen. Stat. § 1-605 et seq.

- 210. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 211. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act. N.C. Gen. Stat. § 1-605 et seq.
- 212. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 213. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

214. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT XXV Oklahoma Medicaid False Claims Act Okla. Stat. tit. 63 § 5053 et seq.

- 215. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 216. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act. Okla. Stat. tit. 63 § 5053 et seq.
- 217. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 218. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 219. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

#### COUNT XXVI Rhode Island False Claims Act R.I. Gen. Laws § 9-1.1-1 et seq.

- 220. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 221. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act. R.I. Gen. Laws § 9-1.1-1 *et seq*.
- 222. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the

Rhode Island Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.

- 223. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 224. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

# COUNT XXVII Tennessee Medicaid False Claims Act Tenn. Code Ann. § 71-5-181 et seq. Tennessee False Claims Act Tenn. Code Ann. § 4-18-101 et seq.

- 225. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 226. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*, and the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.*
- 227. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Tennessee Medicaid Program (i.e. TennCare) false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 228. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 229. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XXVIIII Texas Medicaid Fraud Prevention Act Tex. Hum. Res. Code Ann. § 36.001 et seq.

- 230. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 231. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act. Tex. Hum. Res. Code Ann. § 36.001 et seq.
- 232. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly made a claim to the Texas Medicaid Program for a product that has been adulterated, debased, or mislabeled, or that is otherwise inappropriate, and caused to be presented to the Texas Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 233. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 234. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

# COUNT XXIX Virginia Fraud Against Taxpayers Act Va. Code Ann. § 8.01-216.1 et seq.

- 235. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 236. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act. Va. Code Ann. §8.01-216.1 *et seq*.
- 237. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the

Virginia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.

- 238. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 239. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

# COUNT XXX Wisconsin False Claims Act Wis. Stat. § 20.931 et seq.

- 240. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 241. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act. Wis. Stat. § 20.931 *et seq*.
- 242. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Botox and used false or fraudulent records to accomplish this purpose.
- 243. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 244. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XXXI District of Columbia False Claims Act D.C. Code § 2-308.13 et seq.

245. The allegations of the preceding paragraphs are realleged as if fully set forth below.

- 246. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act. D.C. Code § 2-308.13 *et seq*.
- 247. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Botox and used false or fraudulent records to accomplish this purpose.
- 248. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 249. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

### COUNT XXXII The City of Chicago False Claims Act Chicago Municipal Code, § 1-22-010 et seq.

- 250. The allegations of the preceding paragraphs are realleged as if fully set forth below.
- 251. This is a claim for treble damages and civil penalties under the City of Chicago False Claims Act. Chicago Municipal Code § 1-22-010 et seq.
- 252. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Chicago Department of Public Health false or fraudulent claims for the improper payment or approval of prescriptions for Botox, and used false or fraudulent records to accomplish this purpose.

- 253. The City of Chicago Department of Public Health, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.
- 254. By reason of these payments, the City of Chicago has been damaged, and continues to be damaged in a substantial amount.

### COUNT XXXIII False Claims Act Retaliation Violation 31 U.S.C. § 3730(h)

- 255. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.
- 256. Relator Slade took lawful actions in furtherance of a False Claims Act action, including investigation for, testimony for, or assistance in an action filed under this section and, as such, engaged in protected activity under the False Claims Act and other laws.
- 257. As a Regional Manager for the Allergan Facial Aesthetics Division, Mr. Slade engaged in sales and advised sales representatives on building relationships with current and potential clients. Relator Slade was heavily recruited as a sales manager at Allergan based on his past work as a sales manager at Organogenesis, where he was named regional sales manager of the year and his region led the nation in growth.
- Allergan. Each time Mr. Slade learned of marketing or promotion efforts that did not comply with company policy or FDA regulations, he reported the activity first to his supervisor, Chris Harper. Specifically, Mr. Slade reported to Mr. Harper that it was an unlawful kickback for Business Development Managers to provide free samples of Botox and Juvederm to physicians who treated patients with therapeutic Botox. He also expressed concerns to Mr. Harper about the

misclassification of some physicians as cosmetic when they performed a large number of therapeutic Botox administrations, the diversion of samples by sales representatives to exchange for personal gain, and best price violations as a result of the company's sampling practices.

- 259. Notwithstanding Allergan's obligations under the False Claims Act to provide a non-retaliatory and harassment-free environment for employees reporting compliance violations, Allergan retaliated against Mr. Slade by excluding him from important meetings involving disciplinary issues for the sales representatives he supervised. Allergan employees also retaliated against Relator Slade by reporting to the company's human resources department that he "lost his temper" and spreading false rumors that Relator Slade had problems with anger.
- 260. While employed by Allergan and after his employment was illegally terminated, Relator Slade repeatedly questioned, investigated, and reported internally and subsequently to appropriate Government officials on Defendants' improper practices and billing in connection with Federal and State-funded health care programs in furtherance of a False Claims Act action.
- 261. In October 2008, Relator Slade discovered that Rod Nerad, a Business

  Development Manager in Oklahoma City, had a website to sell Botox and Juvederm injection training to physicians. Although the website was registered under another name, the website directed customers to send payment to Mr. Nerad's home addresss. The website offered training for \$500 a session. It did not offer injection training on other cosmetic products that competed with Allergan products.
- 262. Relator Slade believed that Mr. Nerad was diverting samples from his sample allotment and using them in the website injection training. Relator Slade suspected after viewing the website that Mr. Nerad was personally profiting from distribution of samples by using them in the injection training sessions.

- 263. Relator Slade reported his suspicions to Chris Harper in October 2008. Relator Slade also became aware at this time that Mr. Nerad had complained to Mr. Harper about Relator Slade's looking into Mr. Nerad's activities. Mr. Harper assured Relator Slade that he would investigate. Relator Slade was fired two weeks after reporting Mr. Nerad's activity.
- 264. Defendants without good cause harassed, intimidated, and otherwise created a hostile work environment for Relator Slade in retaliation for his objections to, and reporting of, Defendants' wrongdoing. Defendants knew or should have known that Relator Slade's activities investigating and opposing their unlawful conduct, including investigation for, testimony for, or assistance in and action filed under this section, were in connection with the False Claims Act action.
- 265. Defendants retaliated against Relator Slade for his lawful actions taken in furtherance of a False Claims Act action and the DOJ investigation of Allergan, including, but not limited to, his investigation and assistance in an action alleging Defendants' violations of the False Claims Act and Relator Slade's efforts to prevent further False Claims Act violations by Defendants. Relator Slade reported, at various times, all of the above violations of law recited in this complaint to his superiors at Allergan, prior to filing this action.
- 266. Defendants have a duty under the False Claims Act, 31 U.S.C. § 3730(h) and under 42 U.S.C. § 1985 to refrain from taking retaliatory actions against employees who take lawful actions in furtherance of a False Claims Act action, including investigation for, testimony for, or assistance in an action filed under this section and federal investigations.
- 267. Defendants' misconduct and illegal treatment of Relator Slade and those they derogatorily consider "whistleblowers" has the effect of stifling reports of kickback schemes, and

violations of Medicaid best-price requirements. This treatment effectively warned other Allergan employees that they should not engage in honest and open reporting of Defendants's conduct.

268. The actions of Defendants damaged and continue to damage Relator Slade in violation of 31 U.S.C. § 3730(h) in an amount to be determined at trial.

#### PRAYER FOR RELIEF

WHEREFORE, Relator Slade requests that judgment be entered against the Defendants, ordering that:

- 1. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729, et seq.;
- 2. Defendants pay not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of the Defendants' actions;
- 3. Relator be awarded the maximum "relators' share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state false claims acts;
- 4. Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts;
- 5. Relator be provided with injunctive or equitable relief, as may be appropriate, to prevent further harm to himself and to prevent the harm to others and the public caused by Defendants' retaliation against whistleblowers;
- 6. Relator be awarded all litigation costs, expert fees, and reasonable attorneys' fees incurred as provided pursuant to 31 U.S.C. § 3730(h) and other applicable law;
- 7. Defendants be enjoined from concealing, removing, encumbering, or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;
- 8. Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct;
- 9. Relator be awarded all other damages to which he is entitled, including compensatory and punitive damages; and

10. The United States, the Individual States, and Relator recover such other relief as the Court deems just and proper.

Respectfully submitted,

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Attorneys for Relator Slade

#### **REQUEST FOR TRIAL BY JURY**

Relator hereby demands a trial by jury.

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#### **CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing Complaint was served upon the following individuals as indicated below.

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### U.S. Department of Justice - via Certified U.S. Mail, served on or before October 5, 2011

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